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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/909,186 | 07/19/2001 | Hideji Tajima | 10287.46 | 9114 |
| 27683 | 7590 | 03/29/2004 | EXAMINER | |
| HAYNES AND BOONE, LLP 901 MAIN STREET, SUITE 3100 DALLAS, TX 75202 | | | | CROSS, LATOYA I |
| | | ART UNIT | | PAPER NUMBER |
| | | 1743 | | |

DATE MAILED: 03/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/909,186 | TAJIMA, HIDEJI |
| | Examiner LaToya I. Cross | Art Unit 1743 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 30 December 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-14 is/are pending in the application.
 - 4a) Of the above claim(s) 11-14 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-10 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 30, 2003 has been entered has been entered. Claims 1-14 are pending. Claims 11-14 are withdrawn from consideration as being directed to non-elected subject matter.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 1 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,525,466 to Slovacek et al.

Slovacek et al teach a cylindrical sensor waveguide (120). The waveguide has a surface coating (122) containing a fluorophore reference material (124). An antibody (126) for antigen (128) to be detected is attached to the surface. See figure 4 and col. 8, lines 25-32. With regard to Applicants' claimed base member, the Examiner has construed the coating of Slovacek et al to be a base member. The antigens (128) attached to the base member are chemical substances used for detecting antibodies. The waveguide (120) serves as the carrier around which the base

member is wrapped. When the base member is coated onto the waveguide the base member takes the long, slender shape of the waveguide.

Therefore, for the reasons set forth above, Applicant's claimed invention is deemed to be anticipated, within the meaning of 35 USC 102(b), in view of the teachings of Slovacek et al.

3. Claims 2, 4, and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 4,844,869 to Glass as taught by US Patent 4,447,546 to Hirschfel.

Glass teaches an apparatus for assaying fluid samples. The apparatus comprises an optical fiber (22) inside of a hollow, elongated enclosure (24). The enclosure (24) is a tube made of optically transparent material (col. 5, lines 14-15). This is equivalent to Applicants' transparent container. The enclosure (24) has an entrance face (28) and a terminal end (30). These are the sample inlet and outlet. The enclosure with the optical fiber is coupled to a fluorimeter (43). The entrance face is illuminated by means of a light source with radiation capable of exciting or inducing fluorescence (col. 5, lines 62-67). The induced fluorescence tunnels back to be read by the fluorimeter (col. 5, line 67 – col. 6, line 2). The fluorimeter is equivalent to Applicants' measuring device and identification section, as recited in claim 6, since the fluorimeter reads the fluorescent signals. A means for introducing fluid into the enclosure is present as well as a supply pump (54) controlling the rate of flow of the fluid (col. 6, line 49 – col. 7, line 3; col. 8, lines 25-32). With respect to claim 4, Glass teaches that a mounting means (26) removably mounts the enclosure.

Glass points to Hirschfeld to describe the reactive sites on fiber (22). Hirschfeld teaches that the coating contains coupling sites (44) to which an antibody-antigen complex (46) is attached. Hirschfeld also teaches that the coupling sites are selected so as to immobilize

complexes (46) without appreciably affecting the reactive of the moiety for the complementary portion of the complex. See col. 6, lines 12-48 of Hirschfeld.

It should be noted that Applicants' describe their device by reciting several "sections". The Examiner has interpreted these "sections" to mean the actual structural components of the device. Applicants' claims do not recite any "means plus function" language, thus, the function of the structural components has not been given patentable weight. Should Applicant desire to invoke 112, 6th paragraph, means plus function, Applicants are required to amend the claims to be consistent with the proper 112, 6th paragraph terminology. Applicants should incorporate "means to..." or "means for..." into the claims to describe the structural components by way of their function. See MPEP §2181.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glass in view of US Patent 6,251,688 to Erb et al.

Glass fails to teach a scanning section for relatively moving the light measuring section and container section. Glass also fails to teach a moving section for moving the inlet/outlet to where external containers are mounted.

Erb et al teach an apparatus for measuring binding between a protein and nucleotide. The apparatus contains a fiber assembly (7) with a cylindrical tube (9), similarly to Glass.

Holes (4) serve an inlet/outlet to allow sample to be brought into and out of the cylindrical tube (9). See col. 11, lines 17-30. An optical apparatus is connected to the cylindrical tube to direct light at or near the optical fiber and measures the fluorescence, absorbance, luminescence or polarization of the molecules. The optical apparatus is equivalent to Applicants' measuring device (col. 14, lines 32-50). A sensor cartridge enables a treated surface of the optical fiber to contact a test solution. The sensor cartridge is equivalent to Applicants' scanning section. Erb et al also teaches a means for positioning of the sensor cartridge in the optical apparatus to enable excitation and measuring of fluorescence, etc. The means for positioning is equivalent to Applicant's moving section. See col. 14, lines 51-65. Further, Erb et al teaches a means for acquiring data from the optical apparatus. The means for acquiring data is equivalent to Applicants' identification means. It would have been obvious to one of ordinary skill in the art to use a sensor cartridge/scanning section of Erb et al in the device of Glass to move the treated optical fiber into view of the optical apparatus so that the fluorescence, absorbance or luminescence of the fiber can be seen and the presence/absence of the target analyte can be determined. Further, it would have been obvious to one of ordinary skill in the art to incorporate a moving section into the device of Glass to allow sequential testing of various samples. The moving section will allow the optical fiber to move along several samples and test each samples for the presence/absence of sample analyte.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious, within the meaning of 35 USC 103, in view of the teachings of Glass and Erb et al.

6. Claims 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glass in view of Erb et al as applied to claims 2-6 above, and further in view of Slovacek et al and US Patent 4,031,399 to Klein et al.

With respect to claims 7, 8 and 9, neither Glass or Erb et al teach a base member with chemical structures rolled around a carrier.

Slovacek et al is described above. Slovacek et al further teaches that the cylindrical sensor waveguide (being a base member having antibodies attached wrapped around a cylindrical waveguide) is used in conjunction with an optical processor (300). It would have been obvious to use the optical waveguide in the optical apparatus of Erb et al since the apparatus of Erb et al would provide one apparatus capable of withdrawing and disposing of sample fluid, exciting the optical fiber with light, and providing an output with the measured fluorescence, etc. to denote the presence of a target analyte. In using the apparatus of Erb et al with the optical waveguide of Slovacek et al, one could determine the presence of target analytes using one device, as opposed to separate devices for each step.

With respect to claim 9, Klein et al teaches the conventionality of using a light shield in fluorometer apparatuses to prevent interference from other light sources that may obstruct with the reading. Thus, in order to prevent obstruction of readings, it would have been obvious to one of ordinary skill in the art to include a light shield with the fluorometer of Erb et al to prevent incorrect readings due to the presence of interfering light.

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious, within the meaning of 35 USC 103 in view of the teachings of Glass, Erb et al, Slovacek et al and Klein et al.

Response to Arguments

Applicant's arguments filed December 30, 2003 have been fully considered but they are not persuasive. Applicants' arguments, with respect to the rejection over Slovacek et al, are directed to the chemical structures being in a predetermined fixed location on the base member. Specifically, Applicants argue that Slovacek et al fails to teach such predetermined fixed locations. The Examiner disagrees for the following reasons. As "chemical structures", Slovacek et al teach antibody-antigen complexes and a fluorophore reference materials. Both may be detected to determine the presence or absence of one or more analytes in a sample. At col. 6, lines 52-56, the reference teaches different locations at which the fluorophore reference material may be present – specifically between two surfaces, within the evanescent zone or as a component or label of the reactant coating, as designated by reference characters 20B, 20C and 20D respectively. Thus, it is the position of the Examiner that the location of the chemical structures in Slovacek et al are predetermined by the user.

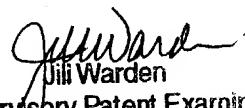
Applicants' arguments, with respect to the Glass reference, are similar in that Applicants allege that the position of the chemical structures are not predetermined. As chemical structures, Glass teaches antibody-antigen complexes. While Glass may not describe the location of the chemical structures, the reference points to Hirschfeld to describe the chemical structures and their location on the fiber. Hirschfeld at col. 6, lines 12-48 teaches that coupling sites are located on the fiber and the antibody-antigen complexes are attached to these coupling sites. The coupling sites are selected so as to immobilize complexes (46) without appreciably affecting the reactive of the moiety for the complementary portion of the complex. See col. 6, lines 12-48 of Hirschfeld. Thus, it is the position of the Examiner that because the coupling sites are selected according to this standard, the sites are predetermined.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 571-272-1256. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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March 17, 2004


Jill Warden
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